

# **Drug and Therapeutics Committee Training Course**

## **Session 11: Drug Use Evaluation**

### **Participant's Guide**

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## PURPOSE AND CONTENT

This session provides information on the concepts of drug use evaluation (DUE), a quality assurance method that is used worldwide, especially in North America and Europe. A broad-based, ongoing, systematic DUE program is valuable in promoting and improving rational drug use in hospitals and clinics.

## Objectives

After completion of this session, participants will be able to—

- Understand the mechanism for implementing and performing a DUE
- Discuss the use of a DUE for improving drug therapy
- Prepare criteria and thresholds for a DUE

## Preparation

Read:

- Participant's Guide
- Management Sciences for Health. *Guidelines for Implementing Drug Use Review Programs in Hospitals*. January 1997.
- American Society of Hospital Pharmacists. *ASHP Guidelines on Medication Use Evaluation*. ASHP Guidelines. 1998.



## INTRODUCTION

The Drug and Therapeutics Committee (DTC) is responsible for many important drug management activities. Two of the most important drug management activities are identifying drug use problems and implementing strategies to ameliorate these problems. The DTC cannot assume that its mission is complete with the evaluation and selection of new drugs for the formulary and the provision of these drugs to practitioners. It must also ensure that these drugs are being used correctly so that patients are receiving the maximum benefit from their drug therapy.

There are many strategies that can be implemented to improve drug use, including educational, managerial, and regulatory methods. This session provides participants with more in-depth information concerning the important managerial strategy of drug use evaluation.

## KEY DEFINITIONS

**Drug Use Evaluation (DUE)**—An ongoing, systematic, criteria-based program of drug evaluations that will help ensure that appropriate drug use is provided. If therapy is determined to be inappropriate, interventions with providers or patients will be necessary to optimize drug therapy. This terminology is similar to drug utilization review (DUR).

**Medication Use Evaluation (MUE)**—Similar to DUE and DUR with an emphasis on improving patient outcomes and individual quality of life. MUE is highly dependent on utilizing a multidisciplinary approach to review drug use so that all professionals dealing with drug therapy will be involved with the process.

## NEED FOR DRUG USE EVALUATION

Irrational drug use has occurred for as long as drugs have been available. In treating patients with modern medicines, there exist several choices of therapy rather than just one that all providers must follow. This increased number of drugs and treatment options serves to increase the irrational drug treatment encounters and, ultimately, poor patient outcomes. Casual observation, as well as more systematic study of prescribing practices, frequently reveals a pattern of diversity among prescribers in the treatment of even the most common conditions.

Polypharmacy is one problem; providers may use three, four, five, and sometimes more drugs to treat the most trivial conditions for the sake of satisfying a patient's need to receive drugs (or the drug seller's need for profit). Other reasons for polypharmacy include lack of diagnostic competence or confidence and an inadequate knowledge of treatment regimens. Other common drug use problems are incorrect drug choices, incorrect dose, prescribing drugs that cause adverse drug reactions, drug interactions, and use of more expensive drugs when less expensive drugs would be equally or more effective.

A drug use evaluation is a system of improving the quality of drug utilization in hospitals and clinics. DUE is an ongoing, systematic, criteria-based program of drug evaluations that will help ensure that appropriate drug use is provided. A DUE can be structured so that it will assess the actual process of administering or dispensing a drug, i.e., appropriate indications, dose, drug interactions, or assess the outcomes, i.e., cured infections, decreased lipid levels, etc. Objectives of a DUE or MUE are as follows:

- Ensuring that the drug therapy meets current standards of care
- Creating guidelines (criteria) for appropriate drug utilization
- Enhancing responsibility/accountability in the drug use process
- Controlling drug cost
- Promoting optimal medication therapy
- Preventing medication-related problems
- Identifying specific drug use problems
- Evaluating the effectiveness of medication therapy
- Stimulating improvements in medication use
- Identifying areas in which further information and education may be needed for health care providers

A DUE system can be established in a short period of time once it is known what the actual drug use problems are. Many of these problems can be identified from other DUE studies, review of aggregate data in the hospital (most costly drugs, most prescribed drugs, adverse drug reaction records, etc.), medical chart reviews, hospital and clinic drug use indicators, or recommendations of DTC members. Regular meetings of the DTC and assessments of quality measurements in the health care system should be able to identify problems that can be addressed in a DUE for resolution.

## **STEPWISE APPROACH TO DRUG USE EVALUATIONS**

The following seven steps outline the basic information necessary to start and maintain a DUE program.

## **Step 1. Establish Responsibility**

This responsibility falls on the Drug and Therapeutics Committee or a subcommittee of the DTC that functions only to monitor drug use evaluations in the hospital or clinic. The DTC should undertake this responsibility with considerable interest, as this process can solve many drug use problems. This has proven to be the case in many countries where this quality assurance function has been fully utilized.

The DTC or a subcommittee must establish procedures that will govern the committee in its activities concerning drug use review and evaluation. As part of the responsibility of the DUE function, it is necessary to establish a plan, outlining which drugs will be a part of the DUE process. This plan needs to be updated and evaluated each year.

## **Step 2. Develop Scope of Activities**

The DTC should assess and then describe the scope of activities necessary within the DUE. The scope can be very extensive or it can focus on a single aspect of drug therapy. Methods to identify drug use problems include ABC/VEN analysis, defined daily dose analysis, adverse drug reaction reports, medication error reports, antibiotic sensitivity results, procurement studies, hospital and primary care clinic indicator studies, patient complaints/feedback, and staff feedback. These screening mechanisms serve to provide the DTC with information concerning drug use that would need further evaluation in a DUE.

Because of the large number of drugs available at a hospital or clinic, the DTC must concentrate on the most important drugs, those with the highest potential for problems, in order to get the most return on the work involved. These high priority areas would include—

- High-volume drug use
- Drugs with a low therapeutic index
- Drugs with a high incidence of adverse reactions
- Expensive drugs
- Drugs that are critically important, including the following categories: cardiovascular, emergency, toxicology, oncology, intravenous drugs, and narcotic analgesics
- Antimicrobial drugs, prophylactic and therapeutic
- Drugs undergoing evaluation for addition to the formulary
- Drugs used for nonlabeled indications
- Drugs used for high-risk patients

### **Step 3. Establish Indicators, Criteria, and Thresholds for Review of the Drug**

Indicators are those aspects of drug therapy that are considered important for rational drug use, e.g., appropriate indications, dose, duration of therapy, contraindications, and quantity dispensed. Criteria are statements that define correct drug use. Establishing criteria is the single most important procedure in a DUE. Criteria for the use of any drug should be established by the DTC using relevant evidence-based literature sources and recognized international and local experts. The criteria for any DUE should reflect what is in the country's standard treatment guidelines (assuming that they have been developed correctly) and any drug use protocols that exist. Credibility of the DUE relies on criteria that are on based evidence-based medicine. Results and acceptance by the medical staff also rely on this process of developing credible criteria.

Criteria should be developed for three to five of the most important indicators for each aspect of drug use. Reviewing larger numbers of indicators will make for a more difficult DUE process and may significantly impair the outcomes of the review. This is not to say that more extensive use of indicators should not be reviewed, only that results are more easily obtained and possibly more meaningful when the scope is narrowed to include only the most important aspects of care.

After developing criteria, the DTC must establish a threshold or standard (benchmark) against which the criteria will be judged. A threshold refers to the percentage of charts or records that will meet or exceed the established criteria for the drug. Ideally this will be 100 percent, but, realistically, a smaller percentage will be more appropriate to account for exceptions to routine drug prescribing. Therefore, a threshold of 90 to 95 percent is typically used for many criteria, but each instance must be carefully analyzed before reaching a conclusion.

A comprehensive list of indicators for appropriate drug use includes the following components:

- Indications—Specific uses for the drug in question
- Dose—Specific doses for any approved indication for appropriate duration
- Quantity dispensed—Correct number of doses administered
- Preparation—Steps involved with preparing a medication for administration
- Monitoring—Laboratory test necessary and intervals of testing during the use of the drug
- Contraindications—Known contraindications
- Drug interactions—Significant drug interactions, including drug-drug, drug-food, and drug-laboratory
- Administration—Specific steps necessary to administer a drug, especially for injectables



- Patient education—Instructions and education that a patient should receive with the drug
- Outcome indicators—Specific outcomes to be realized from the use of the drug
  - Decreased blood pressure, blood glucose, migraine attacks, asthma attacks
  - Decreased visits to the emergency room, decreased hospitalizations
  - Improved patient quality of life (obtained from questionnaires)
- Pharmacy administration indicators
  - Correct cost to patient
  - Accurate billing records
  - Accurate dispensing records
  - Appropriate use of generic drugs or therapeutic equivalents
  - Appropriate use of formulary drugs
  - Appropriate quantity dispensed

## **Step 4. Collect and Organize Data**

DUEs can be accomplished as prospective evaluations or they can be performed retrospectively. A prospective analysis involves the collection of data as the drug is being prepared or dispensed to the patient. Retrospective analysis is done using chart reviews or other data sources to review drug use according to indicators and criteria prepared in advance. The advantage of a prospective review is that the pharmacist (or other reviewer) can intervene at the time the drug is dispensed to prevent errors in dosage, indications, interactions, etc.

Retrospective evaluation, which may involve more of the reviewer's time or require access to medical records, is best accomplished when the reviewer has time away from the patient care areas and distractions. Typically, drug-related criteria that are reviewed in these types of evaluations are as follows:

- Prospective studies (obtained from prescription records)
  - Dose
  - Duration of therapy
  - Dosage form and route of administration
  - Potential drug interactions
  - Appropriate therapy and drug selection (corresponds to standard treatment guidelines)
  - Therapeutic duplication
  - Contraindications
  - Quantity dispensed
- Retrospective studies (obtained from prescription, medical records, laboratory records)
  - Laboratory monitoring
  - Monitoring the therapeutic use of high-cost drugs
  - Comparing prescribing of several physicians
  - Evaluation of indications for drug use (chart reviews)
  - Adverse side effects to medications

- Correct cost charged to patient
- Correct use of generic drugs or therapeutic equivalents
- Patient outcomes from drug therapy

Collection of the data is performed by reviewing a suitable sample of charts or prescription records from the health care facility, usually by selected pharmacy personnel. At a minimum, there should be 50 to 75 records reviewed at each health care facility. The larger the facility and the more practitioners who are available, the larger the percentage of records that would need to be reviewed and analyzed.

An illustrative sample of a collection form, indicators, criteria, and thresholds can be found in Annex 1.

In some countries, computerized systems automatically address the criteria in the process of entering patient information into the computer. Pharmacists then must evaluate any indicators that do not meet established criteria, i.e., dose, drug interactions, duplicate drugs in the same therapeutic class, and others that may appear in the patient record on the computer data entry program. These problems then must be corrected before the drug is dispensed. This system is also useful because of the large number of patients that can actually be evaluated and the subsequent database that would be produced.

## **Step 5. Analyze Data**

Data are collected, tabulated, and analyzed to see if criteria and thresholds are met. The following important steps should be completed when analyzing data:

- Tabulate results for each indicator.
- Analyze results to see if criteria are met and thresholds are not exceeded.
- Determine why thresholds or benchmarks are not met.
- Analyze data quarterly or more frequently.

If a threshold is not met, it may indicate a drug use problem that requires the attention of the DTC.

## **Step 6. Develop Recommendations and Plan of Action**

After completing the data analysis, information is presented to the DTC and a decision is made as to the appropriateness of the information in the DUE. The DTC also must decide on whether to continue, discontinue, or expand the functions of the DUE in question. All drugs that do not meet the thresholds must be evaluated carefully and plans must be made to improve the use of the drug relative to the criteria.

Recommendations should be prepared for the DTC to address the following:

- Inappropriate drug use
- Unacceptable patient outcomes
- Methods to resolve any drug use problem

Recommendations should include specific steps to correct any drug use problem that is evident from performing the DUE. For example, if a specific drug is being prescribed at a high dose, then the recommendations need to reflect this and how the DTC might improve the dosing of this drug. Interventions to improve drug use might include—

- Education, including letters to practitioners, in-service education, workshops, newsletters, face-to-face discussions
- Implementation of drug order forms
- Prescribing restrictions
- Formulary manual changes
- Change in standard treatment guidelines

## Step 7. DUE Follow-up

Follow-up in every DUE is critical to ensure resolution of any unresolved drug use problems. The DUE may have identified new problems that need to be resolved within the health care system. If the problems are not resolved, then the DUE will have little usefulness to the health care system. As a part of a follow-up plan, the DTC must assess the need to continue, modify, or stop the DUE activity depending on the results of each specific drug review.

A DUE should be an ongoing process where drug-related problems are addressed on a regular basis. It is important to consider this a long-term program, one that is continuously updated and revised to reflect current situations and needs within the health care institution.

All programs within the DTC should be evaluated on a yearly basis. This complete evaluation is necessary to look comprehensively at the entire program and analyze its merits and its utility in improving drug use. Programs that do not have a significant impact on drug use should be redesigned so that they can provide measurable improvements. Without improvements in drug use and patient outcomes, the time spent on DUE will be of no value.

Table 1 is an example of a DUE for the antimicrobial ciprofloxacin. This example provides information for the oral formulation of the drug. It does not include all possible indicators concerning this drug, but does provide many of the more important aspects of care.

**Table 1. Sample DUE Criteria for Ciprofloxacin**

Indicator	Criteria	Threshold
Indication	Complicated, chronic, or relapsing UTI Gonorrhea Resistant respiratory tract infections Bone and joint infections Prostatitis GI infections	90%
Dose	Complicated or recurrent infections: 500-750mg bid GI infections: 500mg bid Gonorrhea: 250mg in 1 dose Dose in renal disease – decrease as follows: CrCl 30-50ml/min – 250-500 q 12 h 5-29ml/min – 250-500 q 18 h Hemodialysis – 500mg q 24 h	95%
Duration	Complicated UTI—10-21 days Respiratory—7-14 days Osteomyelitis—4-6 weeks GI—5 days	95%
Contraindications	Pregnancy Children less than 18	100%
Drug interactions	Drugs: theophylline, antacids, iron, sucralfate, probenecid Food: decreased absorption with milk	90%
Outcome	Negative cultures Improved symptomatology No treatment failures	90%

It must be stressed that indicators and criteria for a DUE can be highly individualized depending on the specific needs of the country or region involved.

## WHEN DRUG USE EVALUATIONS GO WRONG

There are some problems in the DUE procedure that will serve to make this process ineffective. Since it is a complicated, multifactorial process, it may easily get bogged down and become an ineffective evaluation. Some of the difficulties and their solutions are—

- Lack of authority and organization—The DUE must have a clear organizational structure, including who develops criteria, collects data, reports results, etc.
- Poor prioritization of problems—Poor prioritization may lead to work on drug use problems that may be insignificant and make meaningful results difficult to obtain.
- Poor documentation—All activities should be documented with a report in the DTC minutes and this report distributed to the medical staff as necessary; documentation should clearly discuss results and recommendations of each DUE.
- Inadequate follow-up—This is one of the most frequent problems to occur with DUE; follow-up and resolution of every problem must be accomplished with each and every DUE.

- Overly intrusive data collection and evaluation—This process can consume many individuals' time and must be kept to a minimum to accomplish the task of the DUE; DUEs in general must not take a significant amount of time from patient care.

The performance of a DUE must be kept in perspective at all times. If a DUE becomes very time-consuming with only minimal results, then it is important to change methodology and restructure the DUE (criteria, data collection, interventions) to provide meaningful results. It is important to understand that the objectives of all DUEs are to identify and correct drug use problems and consequently improve patient outcomes. It is not just an exercise in collecting and disseminating information.

## **ACTIVITIES**

### **Activity 1. Developing a Drug Use Evaluation**

Your DTC has information derived from indicator studies and ABC analysis that shows that use of certain antituberculosis drugs is increasing in the hospitals and clinics of the region. The incidence of multidrug-resistant tuberculosis is increasing in the hospital, but remains at relatively low levels. There are anecdotal reports of inappropriate use (wrong dose, wrong combination of drugs, lack of baseline laboratory studies) of several antituberculosis drugs. The ABC analysis also shows that pyrazinamide accounts for 70 percent of the budget for drugs in this category.

The DTC has revised the standard treatment guidelines for this disease and provided extensive education to physicians and nurses concerning appropriate treatment. DTC members have provided face-to-face education for many providers, especially nonphysician staff. Because this is a potentially significant problem, the DTC recommends that a drug use evaluation be performed to confirm that the educational and standard treatment guideline implemented are effective.

- Develop a DUE for the antituberculosis drug pyrazinamide. This DUE should be designed to assess and ensure the correct use of this drug in treating tuberculosis in your home country.

### **Activity 2. Assessing Possible Overprescribing**

Your DTC has had numerous problems with the use of a single injectable antibiotic, cephax. An ABC analysis shows that this single drug has the highest cost of all formulary drugs and accounts for 10 percent of the entire drug budget for the hospital. This injectable antibiotic is used for its efficacy and safety for many types of serious infections including ARI and septicemia.

Infectious disease consultants have recommended that it be used for very limited serious infections because of its cost and the possible emergence of antimicrobial resistance. Other antimicrobials, including ampicillin and chloramphenicol, are available for these conditions, but have fallen into disuse with the availability of cephax.

- What are the main drug management issues in this activity?
- List some important indicators and criteria for a DUE for this antibiotic.
- What are the most appropriate thresholds for the criteria?
- What are the likely outcomes of a study like this in your institution?

## **SUMMARY**

Drug use evaluation is an excellent method of providing information about drug use and correcting drug use problems. It can be a time-consuming process, but with good criteria that address the most important aspects of care, a reasonable and effective DUE can be established and used over prolonged periods.

The ideal DUE is designed to accomplish the following objectives:

- Ensure that the drug therapy meets current standards of care
- Create guidelines (criteria) for appropriate drug utilization
- Enhance responsibility/accountability in the drug use process
- Control drug cost
- Promote optimal medication therapy
- Prevent medication-related problems
- Evaluate the effectiveness of medication therapy
- Identify areas in which further information and education may be needed for health care providers

DUE methodology has been successful in many parts of the world. By utilizing appropriate planning, development, and follow-up and by implementing appropriate interventions when problems are discovered, improved patient outcomes will be the result.

## ANNEX 1. EXAMPLE OF ESTABLISHED DUE CRITERIA ON DATA COLLECTION FORM FOR AMIKACIN

Date:

Drug:AMIKACIN

Data collector's initials: \_\_\_\_\_

Patient Chart No.							
Diagnosis							
Age/Sex/Weight							
Date Treated							
Criteria and Indicators	Threshold	Observed					
<u>Justification for drug being prescribed</u>							
1. Serious infections caused by susceptible strains of aerobic gram-negative bacteria resistant to gentamicin and tobramycin	95%		Yes No	Yes No	Yes No	Yes No	Yes No
2. Suspected serious gram-negative infections acquired in the hospital with high resistance rates to gentamicin and tobramycin	95%		Yes No	Yes No	Yes No	Yes No	Yes No
3. In combination with an antipseudomonal penicillin when treating serious pseudomonas infections	95%		Yes No	Yes No	Yes No	Yes No	Yes No
<u>Process indicators</u>							
4. Obtain serum creatinine prior to therapy or within 24 hours of initiation of therapy	100%		Yes No	Yes No	Yes No	Yes No	Yes No
5. Loading dose of 7.5mg/kg (IV or IM) based on ideal body weight	100%		Yes No	Yes No	Yes No	Yes No	Yes No
6. Maintenance dosage range of 15mg/kg/day ideal weight (exception: renal compromise)	100%		Yes No	Yes No	Yes No	Yes No	Yes No
7. Therapy changed to tobramycin, gentamicin, or other drug if culture and sensitivity indicate less expensive or more appropriate drug	100%		Yes No	Yes No	Yes No	Yes No	Yes No
<u>Outcome indications</u>							
8. Clinical improvement noted in patient medical records	90%		Yes No	Yes No	Yes No	Yes No	Yes No
9. Fever reduction to normal within 72 hours	90%		Yes No	Yes No	Yes No	Yes No	Yes No